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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/808,555	03/14/2001	Akira Takashima	A33865/090495.0233	3921

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EXAMINER
EWOLDT, GERALD R

ART UNIT	PAPER NUMBER
1644	

DATE MAILED: 09/08/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Advisory Action	Application No.	Applicant(s)	
	09/808,555	TAKASHIMA ET AL.	
	Examiner	Art Unit	
	G. R. Ewoldt, Ph.D.	1644	

--The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

THE REPLY FILED 02 August 2002 FAILS TO PLACE THIS APPLICATION IN CONDITION FOR ALLOWANCE. Therefore, further action by the applicant is required to avoid abandonment of this application. A proper reply to a final rejection under 37 CFR 1.113 may only be either: (1) a timely filed amendment which places the application in condition for allowance; (2) a timely filed Notice of Appeal (with appeal fee); or (3) a timely filed Request for Continued Examination (RCE) in compliance with 37 CFR 1.114.

PERIOD FOR REPLY [check either a) or b)]

a) ☒ The period for reply expires *4* months from the mailing date of the final rejection.

b) ☐ The period for reply expires on: (1) the mailing date of this Advisory Action, or (2) the date set forth in the final rejection, whichever is later. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of the final rejection. ONLY CHECK THIS BOX WHEN THE FIRST REPLY WAS FILED WITHIN TWO MONTHS OF THE FINAL REJECTION. See MPEP 706.07(f).

Extensions of time may be obtained under 37 CFR 1.136(a). The date on which the petition under 37 CFR 1.136(a) and the appropriate extension fee have been filed is the date for purposes of determining the period of extension and the corresponding amount of the fee. The appropriate extension fee under 37 CFR 1.17(a) is calculated from: (1) the expiration date of the shortened statutory period for reply originally set in the final Office action; or (2) as set forth in (b) above, if checked. Any reply received by the Office later than three months after the mailing date of the final rejection, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

1. ☐ A Notice of Appeal was filed on _____. Appellant's Brief must be filed within the period set forth in 37 CFR 1.192(a), or any extension thereof (37 CFR 1.191(d)), to avoid dismissal of the appeal.

2. ☐ The proposed amendment(s) will not be entered because:

   (a) ☐ they raise new issues that would require further consideration and/or search (see NOTE below);

   (b) ☐ they raise the issue of new matter (see Note below);

   (c) ☐ they are not deemed to place the application in better form for appeal by materially reducing or simplifying the issues for appeal; and/or

   (d) ☐ they present additional claims without canceling a corresponding number of finally rejected claims.

   NOTE: _____.

3. ☐ Applicant's reply has overcome the following rejection(s): _____.

4. ☐ Newly proposed or amended claim(s) _____ would be allowable if submitted in a separate, timely filed amendment canceling the non-allowable claim(s).

5. ☒ The a)☐ affidavit, b)☐ exhibit, or c)☒ request for reconsideration has been considered but does NOT place the application in condition for allowance because: *see attachment*.

6. ☐ The affidavit or exhibit will NOT be considered because it is not directed SOLELY to issues which were newly raised by the Examiner in the final rejection.

7. ☐ For purposes of Appeal, the proposed amendment(s) a)☐ will not be entered or b)☐ will be entered and an explanation of how the new or amended claims would be rejected is provided below or appended.

   The status of the claim(s) is (or will be) as follows:

   Claim(s) allowed: _____.

   Claim(s) objected to: _____.

   Claim(s) rejected: *44-48,65,66,69,121 and 133*.

   Claim(s) withdrawn from consideration: *67 and 68*.

8. ☐ The drawing correction filed on _____ is a)☐ approved or b)☐ disapproved by the Examiner.

9. ☐ Note the attached Information Disclosure Statement(s)(PTO-1449) Paper No(s). _____.

10. ☐ Other: _____

9/1/04

G.R. EWOLDT, PH.D.
PRIMARY EXAMINER

DETAILED ACTION

1. Claims 44-48, 65-66, 69, 121, and 133 are being acted upon.

2. Applicant's after final remarks, filed 8/02/02, are acknowledged.

3. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

4. Claims 44-48, 65, 66, 69, 121, and 133 stand rejected under 35 U.S.C. 103(a) as being unpatentable over U.S. Patent No. 5,817,343 (1998) in view of Kim et al. (1998, IDS) and Kellermann et al. (1999, IDS) for the reasons of record set forth in the final office action mailed 4/01/04.

Applicant's arguments, filed 2/17/04, have been fully considered but they are not persuasive. Applicant argues,

"The present invention relates to a method of providing an artificial chemotactic factor gradient created *in vivo*, which can be used to transiently entrap antigen presenting cells circulating through a subject's bloodstream. Once the antigen presenting cells are entrapped, they can be manipulated *in situ* for therapeutic purposes. For example, these cells can be loaded with one or more immunoregulatory molecules, such as a tumor-associated or infectious disease-associated antigen."

"In contrast to the present invention, Burke does not disclose a method for providing an artificial chemotactic factor gradient *in vivo* comprising administering a composition comprising one or more chemotactic factor(s), wherein transient entrapment of antigen presenting cells is achieved. Contrary to the Examiner's allegations, Burke merely provides a method of formulating slow release particles for drug delivery comprising forming a polymer solution/drug mixture in a solvent, removing the solvent from the mixture to form a solid matrix, and fragmenting the matrix at a temperature below the glass transition temperature of the matrix. The focus of Burke is on delivery and stability of labile drugs, not on the creation

of an artificial chemotactic factor gradient in a subject. Therefore, Burke fails to teach or provide any suggestion or motivation to create an artificial chemotactic factor gradient as in the present invention."

Applicant then indicates that the additional references do not cure the deficiency of the primary reference.

It remains the Examiner's position that the combination of references render the invention of the instant claims obvious. First note that Applicant begins by arguing unclaimed limitations, i.e., manipulation of antigen presenting cells *in situ* for various therapeutic purposes. Contrary to Applicant's assertions, the '343 patent does teach a method of providing an artificial chemotactic factor gradient *in vivo*. When a chemical, such as a cytokine, is continuously released from a fixed point in tissue, it will indeed create a gradient expanding out from that point. If that gradient comprises MIP-3β, the gradient will be a "chemotactic factor gradient". Note that the reasons for creating the chemokine gradient set forth in the '343 patent need not be the same reasons as those of the instant application. When combined with the teachings of the secondary references, one of ordinary skill in the art would find adequate motivation for establishing a MIP-3β gradient for the entrapment of antigen presenting cells.

5. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Dr. Gerald Ewoldt whose telephone number is (571) 272-0843. The examiner can normally be reached Monday through Thursday from 7:30 am to 5:30 pm. A message may be left on the examiner's voice mail service. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Christina Chan can be reached on (571) 272-0841.

G.R. Ewoldt, Ph.D.
Primary Examiner
Technology Center 1600

9/1/04

G.R. EWOLDT, PH.D.
PRIMARY EXAMINER